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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,553	01/18/2002	Sing Hiem Yap	9250-37	1503
20792	7590	10/05/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			WANG, LOUISE Z	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 10/05/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,553	YAP ET AL.	
	Examiner	Art Unit	
	Louise Wang	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,6-8,10-13 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 14 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>18 June 2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group III, claims 4, 5, and 14, in the reply filed on 22 August 2005 is acknowledged. The traversal is on the grounds that Examiner has not demonstrated that the claims do not relate to a single general inventive concept, and that the Examiner has not established that there would be a burden in examining the different species of sequences together.

As the Applicant indicated in the reply, the common technical feature of the inventions is the alleged discovery of a previously unknown hepatitis virus. Such a method is disclosed in Nishizawa *et al* (1997) as filed in the IDS submitted on 18 June 2001. Therefore, the technical feature is not a contribution over the art, and thus, the claimed invention cannot be said to have unity of invention.

Applicant's quotations from M.P.E.P. § 803.04 and § 2434 are inapplicable because each nucleotide sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 5 specifically claims multiple SEQ ID NO's, which are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to their unique nucleotide sequence and there is no alignment between SEQ ID NO: 1 and 2 to show significant similarity. As such, the Markush/genus of

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sequences in claim 5 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one sequence from claim 5.

However, upon further consideration, the complement of the elected sequence will be examined with the elected sequence. Therefore, Applicant is only required to elect a species of SEQ ID NO:1 with its complement or SEQ ID NO:2 with its complement.

There were typographical errors in the original requirement for restriction. "Group III" was written as "Group III and IV." Group III should include claims 4, 5, and 14, while Group IV includes claims 6 and 13 only. The species election should have also applied to Group III, which was omitted in the original requirement for restriction as well.

On 1 September 2005, Examiner Wang called the attorney of record, Karen Magri, and clarified the aforementioned typographical errors and reminded her of the species election requirement. Attorney Magri said that the instant application has been transferred to another attorney, Mary Miller, and agreed to forward the message to Attorney Miller. See attached interview summary.

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After Examiner Wang's phone conversation with Attorney Magri, Primary Examiner Stucker called Attorney Miller on 1 September 2005 and explained the above situation. On 16 September 2005, Attorney Miller called and reached the agreement on species election, with traverse, of SEQ ID NO:1. See attached interview summary.

The restriction among the different products that may be used in the claimed methods is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 6-8, 10-13, 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 22 August 2005. Claims 4, 5, and 14 are currently under examination.

For examination purposes, the complement sequence of SEQ ID NO:1 is considered to read on a complementary sequence over the the full length of SEQ ID NO:1.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 18 January 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Duplicate Claim Warning

Applicant is advised that should claim 4 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4, 5 and 14 are directed to an isolated hepatitis Y virus (HYV) genome comprising a nucleotide sequence that hybridizes to a nucleotide sequence of SEQ ID NO: 1 or to the complement thereof, and a composition comprising the nucleic acid. The specification defines SEQ ID NO:1 and the complement of SEQ ID NO:1 as hybridization probes for HYV (page 14, lines 1-10). However, there is no description of the nucleotide sequence, structural or functional characteristics of the claimed isolated nucleic acid or HYV genome. Because claims 4 and 5 do not identify the claimed HYV genome and nucleic acid by SEQ ID NO's, the scope of the claimed genus of nucleic acids or HYV genome is extending unlimitedly to fragments which may include trinucleotides (codons), single amino acids, or fragments that are at least 10 residues in length that would hybridize to the portion that varies from SEQ ID NO:1.

Secondly, claims 4 and 5 refer to a sequence that "hybridizes" to a certain sequence. This is not clear because the subject matter for which protection is sought is not precisely defined. Since no hybridization conditions are included in the claims, they are to be understood as extending to any known prior art nucleic acid molecule.

Therefore, the claims read on nucleic acids with no defined structure and the specification does not reasonably convey possession of these undefined nucleic acids or genomes. For the same reason, the name "hepatitis Y virus" used in claim 4 appears to be an arbitrary term, which is meaningless to the person of ordinary skill in the art in absence of support.

Claims 4, 5, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Examples 6, 7, and 9 provide protocols for how to isolate polynucleotide sequences or the genome of HYV using SEQ ID NO:1 or the complement sequence. The disclosure is a "working hypothesis" as admitted by the applicants in the specification. See page 1, line 6; and page 73, lines 10-14. The applicants have not provided any clear-cut evidence showing that the identified sequence (SEQ ID NO: 1) does in fact belong to a new viral agent. The applicants show that SEQ ID NO: 1 is associated with a transmittable agent (Example 2) and that it is present in dense fractions on a CsCl gradient (Example 8). However, these data cannot rule out the possibility that the alleged new virus represents a strain or a variant of any of the known hepatitis viruses. It may also be identical with a newly discovered virus (TTV), of which the entire genomic sequence has not yet been determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 5, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishizawa *et al* (Biochemical and Biophysical Research Communications, 1997).

Instant claims are directed to a nucleic acid sequence of hepatitis virus that hybridizes with SEQ ID NO:1.

Nishizawa *et al*. teaches oligonucleotides deduced from the sequence of a novel virus associated with hepatitis of unknown etiology (page 92, right column), which reads on to the limitation recited in the current invention.

Thus, the instant invention is anticipated by Nishizawa *et al*.

Claims 4, 5, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sondek *et al* (Proceedings from National Academy of Science, 1992).

The instant invention is as indicated above.

Sondek *et al* teaches the synthesis of trinucleotides, which are encompassed by claims 4, 5, and 14, as they can hybridize with SEQ ID NO:1 or the complement.

Thus, the instant invention is anticipated by Sondek *et al*.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Wang, Ph.D.
Patent Examiner
30 September 2005


JEFFREY STUCKER
PRIMARY EXAMINER